Remarks

In response to the Official Action of June 11, 2003, the applicants have introduced certain subtitles into the specification in general correspondence with the requirements of 37 C.F.R. § 1.77(b) and to improve the readability of the specification. Claims 6 and 7 have been amended to eliminate the reference to "X" as a dimension for the width of the detection zone. Claims 12 and 13, on the other hand, include algebraic expression of the relationships between the width of the detection zone and the width of the first and second regions. These algebraic expressions require some defining reference of the symbol "X", which has been added to claim 12. Claims 6, 7, 12 and 13 are believed to have been amended to overcome any objectionable character. Claim 23 has also been amended to correct an antecedent problem observed by the applicants. If the Examiner has a suggestion for a further amendment to eliminate any remaining objection, the subscribing attorney would welcome a telephone conference to resolve the issue.

Applicants note that several of the dependent claims of the present application were indicated by the Examiner to be allowable if amended to stand in independent form including all the limitations of the base claim and any intervening claims. Applicants have therefore elected to restate claims 2, 14 and 20 in such form. With that restatement, claims 2, 14-18, and 20-22 are now allowable. Applicants that the remaining claims in this application are also allowable based on the following comments.

As to claims 27 and 28, which were rejected under 35 U.S.C. § 112, ¶ 1, applicants first invite the Examiner's attention to page 14, line 28 through page 15, line 3 of the specification, which provides "Even if the sample liquid does not itself absorb radiation or only partially absorbs radiation there is usually a decrease in the reflected or transmitted radiation when the control zone is moistened. As a result the presence of sample liquid can already be determined before a reaction with reagents has taken place in the detection zone." This portion of the specification indicates that the change in reflected or transmitted radiation from

the control zone is a function of the moistening of the control zone by the sample liquid, and not necessarily as a result of any chemical reaction, although a chemical reaction is not precluded and is possible as disclosed in the paragraph appearing in lines 20-29 of page 13 of the specification. This is nothing more than an instrumented measure of the commonly experienced change in physical appearance of a substance when it gets wet, which can take the form of a deepening of color or a dulling of a surface that might be detected by either reflected or transmitted radiation. Even without further explanation, it is clear that claim 27 is supported by the specification. Thus the rejection of claim 27 on the basis of 35 U.S.C. § 112, ¶ 1, should be withdrawn.

Claim 28 focuses on the detection region, not the control region as did claim 27. In the detection region, a reaction of the sample with the analyte takes place, not merely a wetting action (See, e.g., page 1, lines 24-28). According to the paragraph bridging pages 2 and 3 of the specification, "After the detection zone has been contacted with the sample to be analyzed, a first light source is activated in order to irradiate the detection zone. Light reflected from the detection zone or transmitted through the detection zone is detected as a first detection signal. Afterwards a second light source is activated which irradiates a second area of the detection zone which is offset from the first area in the direction of the expected positioning tolerance. The light reflected from this area or transmitted through this area is detected as the second detection signal." As further explained by the paragraph bridging pages 23 and 24, the light sought to be detected from the detection zone is quite different from that sought to be detected from the control zone. These portions of the specification fully enable the invention claimed in claim 28. Further, it is not inconsistent for claim 28 to depend alternatively from either claim 23 or claim 27. Thus the rejection of claim 28 on the basis of 35 U.S.C. § 112, ¶ 1, should also be withdrawn.

Turning now to the prior art rejections, Bolduan et al U.S. Patent 6,055,060 discloses a method and apparatus for the photometric analysis of test elements (T) having a detection zone

(A). Bolduan '060 specifically addresses the detection of two situations; namely, the application of an insufficient amount of the sample liquid, and the unsuitable application of the sample liquid (Column 1, lines 28-31). According to Bolduan '060, a test element is placed on a test strip bed (13) above an illumination unit having a first and a second light source (L_1) and (L_2). The illustrations of Figures 4 and 5 might, in hind sight, suggest that some position variation of test element (T) with respect to the test strip bed (13) could occur. There is also a recognition in Bolduan '060 that "usually only a relatively small part of the evaluation zone is used and information from other areas of the evaluation zone is not considered." (Column 9, lines 25-27) Thus it could be said that the method and apparatus of Bolduan '060 is tolerant of positioning variations of the detection zone.

Bolduan '060 discloses that if a sample liquid is applied to the detection zone (A), then a photometrically detectable change occurs in the detection zone. Activating the first light source (L_1) irradiates a first region of the detection zone, and light reflected from or transmitted by the first region is detected by a detector (D) that generates a first detector signal. Activating the second light source (L_2) irradiates a second region of the detection zone, and light reflected from or transmitted by the second region is detected by a detector (D) that generates a second detector signal. The first and second detector signals are then compared. The comparison is used to determine whether there is a difference in the signals. The value of the difference is employed to detect either of two situations; namely, the application of an insufficient amount of the sample liquid, and the unsuitable application of the sample liquid. There is no disclosure of any determination of whether the first and or the second detection signal has been obtained by illuminating an area situated completely on the detection zone as required by claims 1 and 19. There is also no disclosure of a selection of one of the two corresponding detection signals for the purpose of determining the analyte concentration contained in the sample by analyzing the selected detection signal as required by claims 1 and 19.

Bolduan '060 discloses that if a sample liquid is applied to the detection zone (A) in sufficient quantity and sufficiently evenly that "a possible subsequent quantitative evaluation of the test element, the light sources can be activated one after another and either the measured value or the concentration values which they yield can be used to calculate an average value." (Column 9, lines 11-14) This is not the same as selecting of one of the two corresponding detection signals for the purpose of determining the analyte concentration contained in the sample by analyzing the selected detection signal, which is required by claims 1 and 19. In accordance with Bolduan '060, both sources are used because both the areas they illuminate have been verified to contain enough sample liquid (Column 9, lines 23-24). The disclosure of Bolduan '060 does not anticipate the method of claim 1 or the apparatus of claim 19 of the present application, and the rejection of those claims, and the claims dependent there from on the basis of 35 U.S.C. § 102(e) should be withdrawn.

Markart U.S. Patent 5,889,585 discloses a method for the photometric analysis of a test element (12) wherein a sample is applied to a flat detection zone (14) of the test element (12). The detection zone or measuring field (14) is disclosed to encompass an area that includes and is larger than the measuring areas (26) and (28). The region within the measuring field (14) and outside the measuring areas (26) and (28) could possibly constitute a control region of the detection zone, even though it is not so identified in Markart '585. Sample liquid can be applied to the detection zone (14) so that a first zone (26) comes into contact with the sample liquid earlier than a second zone (28). The zones (26) and (28) are separate from each other. The separation is seen in Figure 2 to be longitudinal with respect to the test element (12), but it might be argued that it is seen as lateral with respect to the measuring optic system (16) in Figure 1. Radiation reflected from (Figure 1) or passing through (Figure 6) the entire measuring field (14) is received by detector (30). The reflection (or transmission) capacity of the measuring field (14) changes in a definite way upon application of a sample liquid that has a chemical reaction with a test substance inside of the measuring field (14), thus enabling a detection of

the presence of the sample liquid. The radiation is supplied to the detection regions or measuring areas (26) and (28) by light sources (22) and (24), and is detected by detector (30). The detector (30) can determine the concentration of an analyte, such as blood sugar, in the sample liquid based on the change in the reflection (or transmission) capacity when sufficient sample liquid is applied to the measuring field (14).

Markart '585 addresses the specific problem arising when an insufficient amount of the sample liquid is applied to the measuring field (14). The evaluation circuit (18) coupled to the detector (30) measures the times t_1 and t_2 for the reflection (or transmission) capacity to change by a predetermined amount in each of the two measuring areas (26) and (28). As disclosed in Column 4, lines 2-17, in the ideal case, in which the entire measuring field (14) is uniformly wetted, there is no time difference. When the measuring filed (14) is not uniformly wetted, a time difference Δt may be observed for the two measured times. A threshold value for the time difference Δt is predetermined. If this threshold value is exceeded, the evaluation circuit (18) produces a warning indication on the indicator unit (20). This signals the user that he should again apply sample liquid (blood) to the measuring field (14) in order to be able to achieve a correct measurement. A second threshold value can also be determined for Δt beyond which a further application of blood may no longer be made because the reaction caused by the first applied blood already has so far progressed that the subsequently applied blood can no longer produce a unified reaction inside of the measuring field (14).

There is NO disclosure in Markart '585 of generating a signal that can be recognized by a user of the test element to terminate supply of sample liquid when the presence of sample liquid is detected in the control region as required by claim 23. In fact, the system disclosed in Markart '585 contemplates the usual small stab wound from which drops of blood are pressed and deposited on a test strip (12), which is then mechanically inserted into a measuring optic system (16). There is no contemplation in Markart '585 of a test situation

in which a test element is already situated in a measuring optic system prior to the application of the sample liquid (blood) to the test element, and the detection of the sample liquid in the control zone is used to signal that a sufficient quantity of the sample liquid has been received so that the user will terminate supplying the sample liquid. It would NOT be obvious to one skilled in the art at the time the present invention was made to modify the system disclosed in Markart '585 to include means for generating a signal that can be recognized by a user of the test element to terminate supply of sample liquid when the presence of sample liquid is detected in the control region as required by claim 23. Thus, the rejection of claim 23, and the claims dependent there from under 35 U.S.C. § 103 on the basis of Markart '585 should be withdrawn.

While Thym et al U.S. Patent 6,036,919 does disclose diagnostic test carriers that include a capillary gap, there is still no disclosure in Thym of any means for generating a signal that can be recognized by a user of the test element to terminate supply of sample liquid when the presence of sample liquid is detected in the control region as required by claim 23. Thus, the rejection of claim 23, and the claims dependent there from under 35 U.S.C. § 103 on the basis of any combination of Thym '919 with Markart '585 should be withdrawn.

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